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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/405,940	09/27/99	HILLMAN	J PF-0346-1-DI

HM22/1024
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EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/405,940

Applicant(s)

Hillman et al.

Examiner

Gerald Ewoldt

Group Art Unit

1644

☒ Responsive to communication(s) filed on Sep 25, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, and 13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 1, 2, and 13, in Paper No. 7, is acknowledged. The traversal is on the grounds that Groups I-IV, IX and X should be examined together because the search for each group would provide information concerning another group, thus the examination of the groups together would pose no undue burden on the Examiner.

These argument are not found persuasive for the following reasons. While the searches of the related inventions may overlap, the fields of search are different and not coextensive. One method of establishing undue burden is a demonstration that the searches are not coextensive; thus, the searches of Groups I-IV, IX and X is found to pose an undue burden on the Examiner because they are not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1, 2, and 13 are being acted upon.

3. Applicant is correct in noting that Group VIII comprises claim 20, not claim 22.

4. Applicant should amend the first line of the specification to update the status of the priority document, i.e., Application No. 08/897,097 is now U.S. Patent No. 6,054,292.

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

A) in the photocopy of the declaration provided to the Office, the signature of Inventor Corley, as well as part of his address have been cut off,

B) the declaration does not include a claim to priority including U.S. Application No. 08/897,097, as disclosed in the specification.

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 2, 13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Applicant is directed to the Revised Interim Utility Guidelines, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999. In keeping with the revised utility guidelines and corresponding training materials (available on the USPTO Website), none of the disclosed uses is a specific, credible, and/or substantial use.

Applicant asserts the polypeptide encoded by SEQ ID NO:1 to be a "T cell receptor beta-like protein". The asserted utility of the protein encoded by SEQ ID NO:1 is as a pharmaceutical composition for the treatment or prevention of diseases ranging from autoimmune disorders to cancer, however, these are not considered to be substantial or credible utilities for the following reasons. The utilities are premised on the similarity of the disclosed full length protein (SEQ ID NO:1) to a human T cell receptor beta chain taught by prior art. However, there is no recognition in the art that sequence identity predicts biological function and therefore a disclosure of sequence identity does not lead one of skill in the art to believe said identity gives a credible use to the claimed protein. It is known in the art that even single amino acid changes or differences in a protein's amino acid sequence can have dramatic effects on the protein's function. For example, Mikayama et al. teaches that the human glycosylation-inhibiting factor (GIF) protein differs from human macrophage migration inhibitory factor (MIF) by a single amino acid residue (see Figure 1 in particular). Yet, Mikayama et al. teaches further that GIF is unable to carry out the function of MIF and MIF does not demonstrate GIF bioactivity (see Abstract in particular). It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. Voet et al., teaches that a single Glu to Val substitution in the subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (see pages 126-

128, section 6-3A and page 230, paragraph bridging columns in particular).

Note that while the specification produces the full-length protein recombinantly, no biological activity is established for the full-length protein or any of the claimed variants thereof. As such, further research would be required to identify or reasonably confirm a "real world" context of use. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved would be required. Therefore, the specification does not fairly disclose a substantial and credible utility for the claimed embodiments.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 2, and 13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a credible utility, for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

10. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

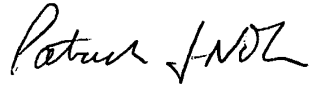
There is insufficient written description to show that Applicant was in possession of any variant of a peptide encoded by SEQ ID NO:1. Variant has not been defined in the specification, however "altered sequence" is defined to include peptides with any and all insertions, substitutions, and deletions, i.e., any peptide or protein. Variant is considered to include at least all "altered peptides", thus, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
October 18, 2000


Patrick J. Nolan, Ph.D.
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